

Applicants: Pablo Rubinstein et al.
Serial No.: 09/855,789
Filed: May 15, 2001
Page 4

REMARKS

Claims 25 and 27-32 were pending in the subject application. By this Amendment, applicants have amended claim 25 to better define applicants' invention. The amendments place the application in condition for allowance or better form for appeal. Accordingly, upon entry of this Amendment, claims 25 as amended and 27-32 will be pending and under examination.

Applicants maintain that the amendments to claim 25 do not raise an issue of new matter. Support for the amendments to claim 25 can be found *inter alia* in the specification as originally filed at least on page 10, second to last paragraph, and on page 22, first paragraph.

Applicants have also amended the title and updated the continuing data for the subject application. Applicants maintain that these amendments do not raise an issue of new matter.

Accordingly, applicants respectfully request that the amendments be entered.

Objections to the Specification

On page 2 of the Office Action, the Examiner stated that the title is not descriptive of the claimed invention and that the specification should be updated to clarify the status of all related applications.

Applicants have amended the title as suggested by the Examiner and have updated the continuing data for the subject application. Accordingly, applicants respectfully request that the Examiner withdraw these objections.

Applicants: Pablo Rubinstein et al.
Serial No.: 09/855,789
Filed: May 15, 2001
Page 5

Rejections under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 25 and 27-32 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner stated that it is not clearly recited in the claim as to what the "therapeutic product" is comprised or consists of.

Applicants have amended independent claim 25 to recite "A therapeutic product obtained from cord blood or placental blood, wherein the therapeutic product comprises white blood cells, less than all of plasma and red blood cells contained in said cord blood or placental blood, and a cryoprotective agent, wherein after freezing and thawing of the therapeutic product, white cell viability in the therapeutic product is greater than 80%." Applicants maintain that the claims particularly point out and distinctly claim the subject matter that applicants regard as the invention. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections under 35 U.S.C. §102

The Examiner rejected claims 25 and 27 under 35 U.S.C. §102(a) as anticipated by Rubinstein et al. (May, 1993), and rejected claims 25, 27 and 28 under 35 U.S.C. §102(b) as anticipated by Boyse et al. (U.S. Patent No. 5,004,681).

Applicants have hereinabove amended claim 25 to recite: "A therapeutic product obtained from cord blood or placental blood, wherein the therapeutic product comprises white blood cells, less than all of plasma and red blood cells contained in said cord blood or placental blood, and a cryoprotective agent, wherein after freezing and thawing of the therapeutic product, white cell viability in the therapeutic product is greater than 80%." Applicants maintain that neither Rubinstein et al. nor Boyse et al. teach a therapeutic product where after freezing and thawing of the therapeutic product, the white cell viability in the therapeutic product is greater than 80%. See e.g. Boyse et

Applicants: Pablo Rubinstein et al.
Serial No.: 09/855,789
Filed: May 15, 2001
Page 6

al., column 50, lines 1-55, and Table V. Accordingly, applicants maintain that neither Rubinstein et al. nor Boyse et al. anticipate the claimed subject matter and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections under 35 U.S.C. §103(a)

The Examiner rejected claims 30-32 under 35 U.S.C. §103(a) as obvious over Boyse et al. (U.S. Patent No. 5,004,681).

In view of the amendments made hereinabove to claim 25, and in view of the preceding remarks, applicants maintain that Boyse et al. do not render obvious claims 30-32 which depend from, and further limit, claim 25. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Allowable Subject Matter

The Examiner indicated that Claim 29 would be allowable if rewritten to overcome the rejection under 35 U.S.C. §112, second paragraph, set forth above and to include all of the limitations of the base claim and any intervening claims. Applicants thank the Examiner for this indication of allowable subject matter. However, in view of the amendments and remarks made hereinabove, applicants request that the Examiner reconsider the allowability of all the pending claims.

Conclusion

In light of the claim amendments and the remarks made hereinabove, applicants respectfully request withdrawal of the objections and rejections set forth in the January 14, 2003 Final Office Action and passage of the pending claims 25 and 27-32 to allowance. If there are any minor matters that would prevent allowance of the claims, applicants request that the Examiner contact the undersigned attorney.


Applicants: Pablo Rubinstein et al.
Serial No.: 09/855,789
Filed: May 15, 2001
Page 7

It is believed that no fee is deemed necessary in connection with the filing of this Amendment. However, if there are unanticipated fees required to maintain the pendency of this application, the PTO is authorized to withdraw those fees from Deposit Account 01-1785.

Respectfully submitted,

AMSTER, ROTHSTEIN & EBENSTEIN
Attorneys for Applicant
90 Park Avenue
New York, New York 10016
(212) 697-5995

Dated: New York, New York
April 2, 2003

By: 
Craig J. Arnold, Registration No. 34,287
Alan D. Miller, Registration No. 42,889



Marked-up Specification Showing the Changes Made

Additions are indicated by underlining; deletions are indicated by strikethrough.

Title on page 1:

HIGH CONCENTRATION WHITE BLOOD CELLS AS A THERAPEUTIC PRODUCT ,~~A~~
~~METHOD FOR AGGLOMERATION OF THE HIGH CONCENTRATION AND A BAG SET~~
~~FOR USE IN CONJUNCTION THEREWITH~~

Paragraph on page 2 before "FIELD OF THE INVENTION":

This application is a continuation of ~~co-pending~~ U.S. Application Serial No. 09/313,816, filed May 18, 1999, now U.S. Patent No. 6,491,678 B1, issued December 10, 2002, which in turn is a continuation of U.S. Application Serial No. 09/128,208, filed August 3, 1998, now U.S. Patent No. 5,928,214, issued July 27, 1999, which in turn is a continuation of U.S. Application No. 08/349,747, filed December 5, 1994, ~~and now issued as U.S. Patent No. 5,789,147, issued August 4, 1998~~, the contents of which are incorporated herein by reference.

Marked-up version of Pending Claims Showing the Changes Made

Additions are indicated by underlining; deletions are indicated by strikethrough.

25. (Currently Amended) A therapeutic product obtained from cord blood or placental blood, wherein the therapeutic product comprises ~~said blood comprising~~ white blood cells ~~having a white cell viability greater than 80% of said white cell viability in said cord blood or placental blood,~~ less than all of plasma and red blood cells contained in said cord blood or placental blood, and a cryoprotective agent, wherein after freezing and thawing of the therapeutic product, white cell viability in the therapeutic product is greater than 80%.

27. The therapeutic product of Claim 25, wherein said cryoprotective agent comprises dimethyl sulfoxide.

28. The therapeutic product of Claim 25, wherein said cryoprotective agent comprises dextran.

29. The therapeutic product of Claim 27, wherein said dimethyl sulfoxide is diluted to 50% with dextran.

30. The therapeutic product of Claim 27, wherein a concentration of said dimethyl sulfoxide is not greater than 10%.

31. The therapeutic product of Claim 27, wherein a concentration of said dimethyl sulfoxide is not greater than 1%.

32. The therapeutic product of Claim 27, wherein an osmolarity of said product is not more than 300 milliosmols.